SUMMARY OF THE
ELAB PBMS WORKGROUP TELECONFERENCE
NOVEMBER 17, 1998

The Performance Based Measurement Systems (PBMS) Workgroup of the Environmental Laboratory Advisory Board (ELAB) met by teleconference on November 17, 1998, at 2:30 pm. The meeting was led by its chair, Mr. Jerry Parr. Action items are given in Attachment A. The list of participants is given in Attachment B. *The purpose of this meeting was to respond to questions on the draft key elements and to begin discussion of a case study on which to test the key elements.*

INTRODUCTION

Workgroup members reported their experiences in using the draft Key Elements to evaluate their assigned method-types in the present case study. The issue of the financial aspects of differing approaches was raised as an additional important consideration in the choice between candidate methods. The reality that samples are generally processed through a laboratory in a production stream, rather than a grouped batch was noted. It was noted that the quality of an analysis is most commonly controlled by its associated regulatory context. Additionally, it was noted application of the Key Elements in the case study is extremely problematic, since available method performance data for existing EPA methods is incomplete, and generally does not refer to current refinements in the measurement technology.

Mr. Parr reviewed these comments and asked the workgroup for suggestions on how he should proceed, considering the workgroup=s report to be presented at ELAB=s December 10, 1998 meeting. It was agreed that the Key Elements are believed to be essential to the success of PBMS implementation, although they developed independently of EPA=s stated goals which were distributed to the workgroup earlier (see Attachment C). Mr. Parr asked members to review these goals in relation to the draft Key Elements. Additionally, the distinction between Data Quality Objectives which address project data requirements and Measurement Quality Objectives, distributed earlier (see Attachment D) should be clarified.

REVISIONS TO KEY ELEMENTS

Experience in application of the Key Elements resulted in a suggestion to replace the term Areference method@ with Avalidated method for analyte/matrix@ since the former has an unintended regulatory connotation. It was agreed that the workgroup=s intentions are that there be an acceptable means for demonstrating state-of-the-art method performance sufficient to satisfy regulatory requirements.

RECOMMENDATIONS

In order to ensure successful implementation of the EPA PBMS program, the workgroup considered possible recommendations. Mr. Parr also proposed that this workgroup consider recommending to ELAB that:

$ ELAB endorse the draft Key Elements,
_ ELAB request that EPA Program Offices explain how their implementation plans will address the Key Elements, and
_ ELAB recommend that PBMS not be implemented until the issues raised in the Key Elements are addressed.

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Mr. Parr requested that the workgroup consideration recommendations that ELAB might make, considering the apparent difficulties. He proposed that there are at least three approaches to demonstrating method performance:

$ method specification in regulations,
_ established reference method, or
_ appropriate analyte/matrix audit materials.

Workgroup members discussed several practical difficulties now recognized with PBMS implementation and agreed to consider additional options to this list.

RANKING OF KEY ELEMENTS
Considering that 12 Key Elements have been identified by this workgroup, Mr. Parr asked the members to consider ranking the elements by importance.

METHODS DATA COMPARABILITY BOARD
Mr. Parr reviewed the related work of the above interagency board, which has published a status report he distributed to the committee earlier (see Attachment E). He asked members to review this report for issues relevant to this workgroup=s work.

NEXT MEETING
The next meeting of this workgroup is scheduled for December 1, 1998.

Attachment A

ACTION ITEMS
ELAB PBMS Workgroup Teleconference
November 17, 1998

No.	Action	Date to be Completed
1.	Members are to review EPA=s stated goals for PBMS with the draft Key Elements for consistency.	
2.	Members are to review the proposed recommendations to ELAB.	
3.	Members are to consider ranking the Key Elements by relative importance.	
4.	Members are to review the issue paper by the Methods and Data Comparability Board.	

Attachment B

PARTICIPANTS
ELAB PBMS Workgroup Teleconference
November 17, 1998

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Attachment C

Goals for the EPA Performance Based Measurement System (PBMS)
Approach to Regulatory Development

1. Provide a simple, straightforward way for the regulatory community to respond to specific measurement needs with reliable, cost-effective, methods.

2. Emphasize project- or application-specific method performance needs rather than requiring that specific measurement technologies be used in order to avoid costly measurement overkill.

3. Encourage the use, by the laboratory community, of professional judgement in modifying or developing alternatives to established Agency methods.

4. Employ a consistent way to express method performance criteria that is independent of the type of method or technology. This includes articulating measurement needs in qualitative and quantitative terms.

5. Foster new technology development and continuous improvement in measurement methodology, by providing qualitative and quantitative targets for identified measurement gaps to method developers and other researchers.

6. Encourage the measurement community to give the Agency feedback on new monitoring approach successes as well as failures in order to expand our knowledge of new or modified approaches and to assist others by helping to disseminate this information to the wider monitoring community.

Measurement Quality Objectives are the quantitative and qualitative statements or representations of the data quality required of the analytical laboratory measurement process if it is to satisfy (comply with) decision objectives of a program or project.

These program- or project-specific statements or representations serve as the *criteria* (see Checklist of Initial Demonstration of Method Performance) against which the performance of a proposed method or method modification is compared to determine the acceptability of that method when applied to samples representative of the program or project. Depending upon which of the data quality characteristics is considered, the criteria may be in the form of a numerical value which must be achieved (e.g., precision), a range of values within which the proposed method must perform (e.g., bias, recovery), or a statement relating to the nature of controls in place during the demonstration (e.g., source of reference or spiking materials). While the last of these is not a performance criterion *sensu stricto*, it represents a criterion for the acceptability of the demonstration.

Note that the above relates to performance A. . . when applied to samples representative of the program or project.@ This clarification is included because the Arepresentativeness@ of the sample is frequently not under the control of the analytical laboratory. The contribution of sample design, collection, and handling prior to receipt by an analytical laboratory often is responsible for a major share of the Atotal measurement error@ that must be considered in making program- or project-related decisions based upon measurement data. If one were to assume that the error contribution from the Afield@ was negligible, and that samples received at the laboratory were truly representative of the conditions under evaluation by the program or project, then the measurement quality objectives would correspond to the total measurement uncertainty (error) that can be tolerated.

Where a long history and appropriate Afield controls@ yield a consistent error level attributable to pre-laboratory activities, a finite relationship between total allowable error and the performance requirements for the laboratory analytical process is straightforward:

Total Allowable Error-Field Error Contribution = Maximum Allowable Lab Error

It must be noted that the Alab error@ is not just a function of the performance characteristics of the method used, but rather also the skills of the operator and the facilities/conditions of the demonstration. However, in the absence of a multi-laboratory evaluation of a method, reported Amethod performance@ is usually synonymous with *the performance of the method by an operator under a given set of conditions.* As conditions in the laboratory are optimized for the method and the operator gains sufficient experience in its performance, the potential of the method and the actual performance achieved should converge.

Methods and Data Comparability Board (MDCB)
Performance Based System Workgroup

Issue Paper: Toward a definition of a Performance-Based Approach to Lab Methods

EXECUTIVE SUMMARY

The MDCB endorses the concept of a performance-based approach to laboratory methods (PBMS) as an enhancement to both ambient monitoring and compliance programs and encourages the National Water Quality Monitoring Council to adopt this recommendation. Key aspects of the MDCB endorsement of PBMS include a) the need to establish measurement quality objectives (MQOs) or data quality objectives (DQOs) for each parameter reported; b) the need for reference methods to demonstrate the ability to meet these MQOs or DQOs; c) the need for adequate reference materials to assist labs in demonstrating the appropriateness of a given method (prescriptive or PBMS); and d) the need for labs to adequately document method performance.

With the evolution of different water quality monitoring and analysis methods among organizations, even within a single agency, there have been two significant and related consequences in terms of our ability to assess the quality of our nation=s waters. In ambient water quality monitoring, reliance on prescriptive methods has been accompanied by infrequent documentation of associated method performance. This has resulted in unknown or poor quality data and uncertainty in the comparability of data collected across programs or organizations. Consequently, monitoring groups outside the agency collecting the data do not know which information can be used with confidence, resulting in limited data sharing across organizations. This is a significant problem because: (a) assessments of aquatic resources on broad geographic scales (basins for example) or from State to State are not easily feasible and (b) opportunities for increased resource efficiency or for minimizing duplication of efforts are missed.

The reliance on prescriptive methods in compliance water quality monitoring has also had significant deleterious consequences. Due to current bureaucratic and administrative constraints, it is time-consuming, resource-intensive, and cumbersome to modify existing methods or add new improved methods to the Federal Register. The result is that more sensitive or cheaper, faster methods have not been easily implemented or encouraged in compliance monitoring.

Many organizations have recognized the limitations of a prescriptive methods approach and after much deliberation, the Interagency Task Force on Monitoring Water Quality (ITFM) recommended that a performance-based approach be used to address these limitations. A performance-based approach is a process that permits the use of any appropriate method that demonstrates the ability to meet established method performance criteria (e.g., sensitivity, bias, accuracy) and complies with specified data quality needs.

The Methods and Data Comparability Board (MDCB) of the National Water Quality Monitoring Council advocates a performance based system (PBMS) as one of its top priorities in providing a mechanism that will: (a) enhance data comparability among various monitoring programs and databases, (b) encourage the implementation of better or more cost-effective methods, and (c) provide data of known quality. The MDCB recognizes that several types of performance-based systems have been proposed or used by different programs and that there is a need to develop a unified national approach. The MDCB also recognizes that there are several issues outstanding concerning how such an approach would be

implemented in compliance or ambient water quality monitoring. ***The MDCB and the National Council should act as the focal point for harmonizing existing or proposed performance-based systems so that a sound, unified interagency approach can be achieved and implemented in an intelligent, fair manner***. The purpose of this first issue paper is to present the MDCB=s position concerning the need for, and the concerns regarding, the implementation of a performance-based system for water quality monitoring methods. Specifically, this paper:

- presents MDCB=s definition of a performance based methods system and demonstrates that it embraces the conceptual ideas expressed by most organizations and agencies
- identifies advantages and current issues in implementing a PBMS in compliance and ambient monitoring
- provides a framework for validation of PBMS measurements
- discusses the feasibility of extending a PBMS approach to method-dependent parameters and field methods
- outlines future activities intended to help address some of the issues and concerns raised regarding the implementation of a PBMS

WHY IS A PRESCRIPTIVE METHODS APPROACH STILL USED BY MANY ORGANIZATIONS?

Currently, most state and federal agencies require prescriptive methods in their monitoring or regulatory programs for several reasons, most of which are perhaps more pragmatic than scientifically-based. Major reasons cited for using prescriptive methods include the following.

- They are generally well documented in terms of their performance characteristics (precision, bias, etc.), at least under certain known conditions or for certain matrices (often reagent water). Therefore, data can be evaluated with a similar matrix using a prescriptive approach. Without adequate validation, this same statement can not be made for a PBMS.
- They have generally been used by many laboratories and organizations and so are familiar to the personnel collecting and interpreting the results of the method.
- The agency requiring the data can have a relatively simple and clearly defined methodology structure and correspondingly, a less intensive and costly quality assurance program (i.e., fewer and simpler lab audits or data quality checks).

All of the above reasons have been used by State and federal agencies to defend relatively cost-effective (though narrowly defined) laboratory certification programs and straightforward data quality control programs.

DISADVANTAGES OF A PRESCRIPTIVE METHODS APPROACH

The disadvantages of prescriptive methods lie, in part, in some of the assumptions made concerning their true performance characteristics. Both in the regulatory arena and in the scientific literature, there are many examples demonstrating that the performance characteristics of a given method in various Areal-world@ matrices (e.g., certain types of wastewater effluents, groundwater, or leachate) may be far different

(poorer) than those same method characteristics based on laboratory reagent water or other relatively simple matrices. For example, many States have recently introduced into their water quality standards minimum quantification levels for several chemicals such as metals, recognizing that the published detection limits for these prescriptive methods are not consistently achievable with many wastewater matrices.

In general, unless a laboratory conducts rigorous quality control analyses (required in many newer compliance methods) on the matrix it is analyzing, the performance characteristics reported for the method cannot be assumed to have been achieved. Thus, prescriptive methods, as currently implemented, could give a potentially false sense of known and acceptable data quality and may encourage less rigorous quality control programs (both within a lab and within the agency requiring the data) than is actually needed.

Other disadvantages of prescriptive methods are:

- different agencies or programs have often developed and published different prescriptive methods for the same parameter making it difficult to determine the degree of comparability in data among programs;

- there is less incentive for laboratories or manufacturers to design and evaluate potentially better methods; i.e., methods that are more sensitive, more reliable, cheaper, faster;

- method improvements, even if well documented, are difficult to implement because of regulatory and administrative constraints associated with using a prescriptive method framework; and,

- actual method performance and associated data quality is often unknown.

WHAT IS A PERFORMANCE-BASED METHOD SYSTEM?

Previous work by the ITFM and several agencies independently emphasized the need for data quality objectives (DQOs) or measurement quality objectives (MQOs) in performing assessments. MQOs are statements that contain specific units of measure such as: percent recovery, percent relative standard deviation, standard deviation of X ug/L, or detection level of Y ppb. DQOs are statements that define the confidence required in conclusions drawn from data produced by a project. Both concepts are central to a performance-based system approach.

Several definitions of a PBMS have been proposed by different organizations and reviewed by the MDCB. Various distinctions have been made between a performance-based *methods* system and a performance-based *measurement* system. The former generally implies the use of reference methods and their associated performance criteria as the standard of comparison to other methods while the latter requires only stated performance criteria as the comparison standard. ***The MDCB endorses the need for reference methods as well as stated performance criteria, which have been shown to be achievable***. All of these definitions have in common the concept that PBMS is a framework that permits the use of any appropriate sampling and analytical technology that demonstrates the ability to meet established performance criteria and complies with specified DQOs and MQOs of the project in which the sampling and analytic technology is employed. To establish and preserve the credibility of performance-based systems, performance criteria, such as precision, bias, sensitivity, specificity, detection level, and rates of false positives and false negatives must be designated and a sample collection or sample-analysis method-validation process must be documented. Whether we call PBMS a Amethods@ system or a Ameasurement@ system, the basic goals are the same - to provide information of known quality that will satisfy user needs. It is generally agreed by the MDCB that the implementation of a PBMS, with corresponding required data qualifiers entered into

a multi-user database, will allow divergent data from numerous environmental programs to be used for many purposes.

For a PBMS to be successful, the following basic conditions must be met:

- DQOs or MQOs must be set that realistically define and measure the quality of data needed. These objectives must be compared to the attributes of the data to be used in the measurement system.
- Reference methods must be made available that meet these objectives, or objectives should be dependent on results of multiple measurements on known samples using different methods. There are a number of consensus organization methods and previously developed EPA methods that are available as reference methods for many frequently measured analytes.
- The selected methods must be capable of meeting the DQOs or MQOs.
- There must be documented proof of method adequacy. {**Need to define adequacy**}
- Reference materials covering a variety of relevant matrices, containing the analytes of interest, should be available either through preparation using known concentrations or through round robin testing of unknowns (**this is a significant stumbling block)**
- Method ruggedness must be demonstrated. (**Need to define ruggedness**)
- For compliance based programs, mechanisms for determining liability must be clarified.

ADVANTAGES OF USING A PBMS APPROACH

There are two general advantages to implementing a PBMS rather than a prescriptive methods approach. One advantage pertains to enhancing method technology: development of better, faster, cheaper methods or new methods to satisfy new or modified programs. Thus, encouraging PBMS ensures that (a) methodologies are appropriate for the matrix being tested, (b) new technologies are adopted much more readily than when using prescriptive methods, and (c) labs can readily modify methods where such modifications are documented as still being effective and reliable.

A second type of advantage pertains to interpretation of data already collected. Using a PBMS approach and documentation of data qualifiers in a database, data users can more easily decide which data can and should be used for their project needs. Thus, encouraging a PBMS in this sense ensures that (a) data of known quality are reported, (b) data may be used appropriately for several different purposes or by several organizations, and (c) comparability of data collected by different programs can be determined.

EXAMPLES OF PROGRAMS THAT USE A PBMS APPROACH

There are several examples where a PBMS has been used successfully to generate environmental data of known quality. One example is the NOAA Status and Trends Program, which has been ongoing for over 10 years. This program has been non-restrictive in terms of methodologies, allowing participants to use any measurement system they felt was appropriate. However, this program ensured comparable data quality among laboratories and methods systems by having: a) well defined DQOs that were shown to be achievable using a variety of methods; and b) a continuing inter-comparison program using reference samples, which are representative of the matrix being evaluated, so that labs could demonstrate their ability

to meet the DQOs. This program has been successful largely because of the inter-comparison data on reference samples, which has allowed both labs and data validators to assess the accuracy of the results from an individual lab and determine whether methods were indeed adequately validated. Proving that a method works on an unknown sample that is not simply spiked reagent water is the best demonstration of method adequacy.

Implementation of a PBMS within EPA=s Office of Water (the primary regulatory office responsible for requiring water quality monitoring), is proceeding with a proposed PBMS process to reduce the regulatory burden of prescriptive methods required under the Clean Water Act and the Safe Drinking Water Act. This proposal (FR March 1997) applies to chemical methods and would allow analysts to use professional judgement to modify and develop alternatives to established EPA methods. This process is very similar to the definition of PBMS proposed by the MDCB. In anticipation of an Agency-wide shift to a performance based process, EPA=s solid waste program updated its SW-846 methods in a PBMS format which included method performance criteria. An initial and continuing demonstration of method performance are required in this update. In this SW846 program, implementation of PBMS does not negate the need or use of standard or consensus methods; it only eliminates the mandate that they be used. Other examples where a PBMS has been applied successfully include the EPA=s Pesticide Registration program under FIFRA and the Federal Drug Administration=s drug approval and pesticide analysis program.

THE ROLE OF PBMS IN COMPLIANCE AND AMBIENT MONITORING

There are some differences in the applicability of PBMS to regulatory versus ambient monitoring programs. Compliance monitoring is fundamentally different from ambient monitoring in that data collected for compliance purposes has legal ramifications and could be used by the regulatory agency to support enforcement actions such as violations, fines, law suits, and even facility closure. Thus, any methods approved for use in collecting compliance monitoring data must be reliable and provide the desired sensitivity, accuracy, and precision required by the particular regulatory program. Although both ambient and compliance monitoring equally require data of high quality, there is generally greater liability associated with compliance monitoring data.

Liability is one of the major issues currently being debated in regards to implementing a PBMS. Whereas the USEPA, other federal agencies, or States may have the chief liability for method performance and data quality within a prescriptive methods system, under a PBMS it is less clear who encumbers the liability for the data generated. It is likely that the data generators (contract laboratories or permit-holder laboratories) and/or the data users (i.e., permittees who use a contract laboratory to analyze samples for their facility) could be liable for incorrect or poor quality data, even if the method was approved for use under a PBMS. In some cases, the State or tribal agency may ultimately be liable for problems caused by poor data because ultimately, the State approved the use of the method under a PBMS. Clearly, this is an issue that needs to be resolved before any PBMS is implemented.

A related legal issue associated with using a PBMS in compliance monitoring is that courts of law may be reluctant to recognize results from an alternate or new method even if it has been shown to achieve the same or better level of performance as the prescriptive (reference) method previously required. It needs to be made clear who or what organization would be legally responsible for upholding or denying the use of a certain method in a court of law or who ultimately approves methods under a PBMS. Under the current proposal by EPA=s Office of Water, pre-notification of regulatory bodies would be required. This approach does ensure that PBMS is used with some foreknowledge, although it does not address the liability issue.

Despite the challenges involved with implementation, a PBMS is potentially advantageous in both

compliance and ambient monitoring. In compliance monitoring, both the regulatory agency and the regulated facility need accurate information to ensure that correct environmental management decisions are made. Methods that yield more accurate data, or that attain more appropriate sensitivity given federal or state/tribal standards, should be preferred in compliance monitoring. Under a PBMS, such method innovations or refinements are encouraged. This could be especially relevant in those cases in which a particular facility matrix demands certain modifications to a given method.

In ambient monitoring, the monitoring agency also needs to have accurate information to help prioritize and implement appropriate management strategies. More efficient, more accurate, or less costly collection and analysis methods for ambient samples should be preferred because the overall efficiency and quality of the monitoring program would benefit. Under a PBMS, such method improvements could be explored and implemented relatively easily.

Another area in which a PBMS would benefit ambient monitoring is in determining the comparability and relative quality of data collected by different monitoring organizations across the country. Currently, each organization may have its own methods for certain types of parameters (e.g., biological assessments). It is difficult to determine which, if any, of these methods produce comparable data and to what extent regional or national status and trends can be discerned given that data are collected using different methods. Under a PBMS, this situation could be improved because each monitoring entity would need to demonstrate the performance characteristics of their method and ensure that those characteristics are achieved routinely. As a result of this process, it would be possible to determine which methods are comparable, which data can be combined for status and trends analyses, and what data quality objectives could (and should) be required to address a given question. Another benefit of using a PBMS for ambient monitoring is that different organizations may be able to use each other=s data, thereby reducing the number of sites that each one needs to sample. Alternatively, more sites could be sampled by the combined organizations for the same cost, increasing efficiency and the information database.

REQUIREMENTS FOR VALIDATING PROTOCOLS IN A PBMS

Ultimately, PBMS is no different from Good Laboratory Practice (GLP) in terms of the types of data that must be provided to ensure comparability. The biggest difference between PBMS and the use of existing reference methods is the degree of prior validation of the methods, which makes it extremely important to have demonstrated the appropriateness of the PBMS approach on the matrix of choice. Additionally, many laboratories still rely on existing reference methods because they do not have the resources to validate a PBMS. Increasing flexibility in existing reference methods is an important step towards ensuring that a PBMS is workable.

In follow-up papers, the MDCB plans to evaluate and recommend the minimum data set required by a laboratory to document the validity of a PBMS protocol. The MDCB is reviewing data quality requirements used by many organizations including USGS, USACE, and NOAA. Both EPA=s Environmental Monitoring Management Council (PBMS checklist) and EPA=s Office of Water (PBMS checklists) have proposed method performance criteria. Both of these checklists are extensive and often also require the provision of data that does not exist for many of the reference methods. These checklists must be evaluated critically to identify both roadblocks to and opportunities for the implementation of PBMS. The Methods Board has identified techniques not often used by laboratories to evaluate data quality, such as evaluating standard curves with back calculations or rotating levels of check standards, which, if encouraged, may eliminate some of the checklists= requirements. The table below indicates which data should be provided by the lab to validate performance and to ensure comparability of data

Note that many of the items suggested here are the same as those which should be available for

prescriptive methods, and therefore the burden on an auditor or user to evaluate data is not necessarily significantly increased under this approach, as long as the auditor focuses on data review rather than method review per se. It will however require an increased level of expertise by auditors.

REQUIREMENTS FOR VALIDATION OF A PBMS PROTOCOL

Item	Reference Method used	PBMS Used
Specific reference method being compared to.		X
Deviations from the method (with explanation) if modified method.	X	X
Specify matrix being tested		X
Method blank results.	X	X
Other appropriate blank results	X	X
Desired rate of false negatives and false positives		X
Required MQOs and/or DQOs		X
Reference sample results. (reference sample should mimic the matrix of interest and be chosen to test method modifications near the desired action level)	X	X
Spike, duplicate spike, and duplicate sample results, where appropriate	X	X
Surrogate results (if applicable).	X	X
Tuning results to meet method specifications (if applicable).	X	X
	X	X

Calibration checks and calibration specifications. Bmultipoint or single point, as applicable		
Any appropriate data qualifiers	X	X
Interference checks if applicable	X	X
Method detection limits.	X	X
Sampling and preservation, testing all relevant parameters	X	X
Project Decision Level, where appropriate	X	X

[Note: Each of these table entries will be defined more completely as guidance in an appendix to this document].

THE PBMS PROCESS

Defining the performance criteria of a method that meets DQOs is the first step in initiating a PBMS. Statistically based quality-control criteria for replicate measurements and calibrations should be established as a measure of required precision. Bias limits are typically determined by analyzing spiked samples, standard reference materials, and performance-evaluation samples. Long term method detection limits are desirable to determine the application of a method to monitoring needs or regulatory requirements. **[Ref USGS=s efforts as an illustration]** The performance range of a method also should be determined. The method must not generate background or interference that will give unacceptable rates of false qualitative or quantitative information. If a method is considered to be applicable for multimedia, then documented evidence should be available to support this use.

Achieving these goals in all media requires training, the availability of matrix-specific performance-evaluation materials, the implementation of a laboratory-accreditation process, and the systematic audit of activities. The current stock of standard chemical and biological reference materials and performance evaluation samples is limited or, in some cases, nonexistent and needs to be developed or expanded to cover a wider range of constituents and media.

The training requirements to implement a PBMS, and to reach some level of national comparability, are extensive because of the diversity of water quality monitoring programs and data requirements. The MDCB recognizes that adequate training and education of data generators, auditors, and users is central to the successful implementation of a PBMS. A "National Curriculum" **[a training manual?]** needs to be established and should include formal and informal components. **[Is it appropriate for MDCB to participate in this?]**

The Methods Board also recognizes the need for laboratory accreditation with periodic review of activities as an important element in a PBMS. To this end, the MDCB supports laboratory accreditation efforts by the National Environmental Laboratory Accreditation Program (NELAP) and other organizations. Continued review of protocols by outside auditors will help to make PBMS sufficiently rugged when used broadly. PBMS in the Context of Method-Defined and Field-Measured Parameters

Certain parameters, such as BOD, Oil and Grease, and most biological, microbiological (somewhat less so), and field-measured parameters, are Amethod-defined@ indicating that the results obtained are dependent on the particular method used. Unlike many chemical parameters, in which data accuracy and

other elements shown in the preceding table can be verified in a number of objective ways, data derived from method-defined protocols cannot often be objectively verified outside the method itself. We are unable, for example, to conduct meaningful "matrix spikes" for biological assessments or toxicity in aquatic field methods. The current EPA PBMS proposal excludes such methods from a PBMS approach for this reason. However, the MDCB believes that these types of parameters can and should be subject to a PBMS; certain method performance characteristics such as sensitivity, precision, and performance range, can be quantified and compared for method-dependent or field methods.

A key factor in the implementation of a PBMS for method-defined parameters is the use of defined reference conditions or field reference sites. Just as analytical methods depend on the availability of appropriate reference materials to verify and document certain method performance characteristics (notably accuracy, sensitivity, and bias), method-defined parameters require either field or synthetic reference samples in which at least the general level of the parameters is thought to be known. For example, known clean, well-aerated streams or groundwater could be used to demonstrate method >blank= performance for toxicity or BOD. Alternatively, there may be other >reference= sites that could provide a quantifiable or consistent level of the desired parameter. A certain natural spring may produce a relatively consistent level of toxicity (due to the physicochemical characteristics of the water) or microbial density (due to the source of the water). Various types of method validation and comparability demonstrations using a PBMS-type of approach have begun in several state programs for biological assessment methods, EPA=s culture and sediment toxicity testing methods, and zooplankton enumeration, and species richness methods for the Chesapeake Bay Program. Similar kinds of method characterization and documentation have also begun for microbiological pathogen methods within EPA=s Office of Drinking Water and Ground Water.

NEXT STEPS FOR THE MDCB

Following National Water Quality Monitoring Council review and approval of this Issue Paper, there are other important tasks required to bring PBMS issues to closure for the MDCB. These tasks are estimated to require the rest of 1999 for completion.

MDCB tasks include establishing the kinds of required data, the frequency of such data, possible reporting formats for that data, and caveats for a PBMS (e.g. the kinds of interference often not checked adequately in environmental data) to maximize the likelihood that a PBMS will be used effectively. This will include recommendations regarding the minimum data set required to document the validity of a PBMS protocol. The MDCB will also produce a compilation of possible reference materials to assist labs in evaluating method modifications. The MDCB will also conduct additional tests of the PBMS validation requirements listed in this paper, using different sets of analytes, to verify it=s completeness and to provide examples in a future document. A further task will be the initiation and completion of pilot studies of the PBMS process. Additionally, the MDCB may review the availability and adequacy of reference methods for common analytes. In conjunction with the Methods Compendium workgroup within the MDCB, the MDCB will identify important parameters that are in need of reference methods that have methods in need of further refinements.